pages 40-53 of the specification.

(c) dosages are discussed at pages 29-32 and 34-35 of the specification, and safe dosages are known for many of the contemplated immunogens.

(d) the human immunization schedules which resulted in favorable epidemiological effects on diabetes are known (see, e.g., table I, on page 87, referring to vaccination with BCG at birth in 1988 in Ireland, France and Austria). Those dosages of other immunogens, such as pertussis, which, upon late administration, increased the incidence of diabetes are also known and presumably would still modulate diabetes (although more favorably) if given earlier.

The principal parameters of the immunization schedule are the timing of the first dose, the total number of doses, the interval between doses, and the size of the doses. Several preferred schedules are set forth on pages 40-53. All of the preferred schedules begin prior to 56 days after birth, and most are initiated when the subject is less than 42 days old. Indeed, the subject can be less than 8 days old (page 51, line 10), even 1 day old (see page 79, line 9). The preferred interval appears to be less than 28 days (see, e.g., page 40, lines 25-26) and can be at least as short as one week (see page 56, lines 9-11) or even two days (see page 79, lines 9-10). The number of doses can be as few as three, see page 56, lines 17-21, or fewer, see page 56, lines 24-26. It can also be greater, such as nine (see page 79, lines 9-11) or even 26 (see page 56, lines 7-11).

In general, the response is expected to be increased by administering the immunogen earlier, more often, at shorter intervals, and at higher doses. Therefore, if a preferred schedule is tried, and found inadequate, one or more of the schedule parameters would be changed, i.e., starting earlier, giving more doses, reducing the dose interval, or increasing the size of each dose (or at least of the first dose). If the anti-